DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95063d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

WARNING LETTER

FLA-05-02

October 13, 2004

Scott W. Orren, President
Cut Right Seafood Inc.
6478 San Casa Drive, Unit B
Englewood, Florida 34224

Dear Mr. Orren:

We inspected your firm, at the above address, on June 18, 2004, and found that you have serious deviations from the seafood HACCP regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your canned pasteurized crabmeat is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviation is as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for canned pasteurized crabmeat to control the food safety hazard of pathogen growth and toxin formation, specifically *Clostridium botulinum*.

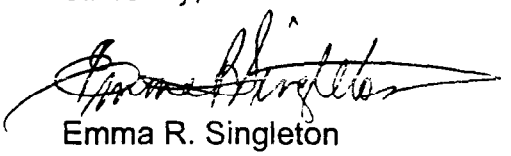
In addition, during our inspection, we found that your firm's HACCP plan for histamine-forming fish had not been reassessed since June 7, 2001. Pursuant to 21 CFR 123.8(a)(1), you are required to reassess the adequacy of your HACCP plan(s) at least annually or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way. Our compliance review of that plan, furthermore, found numerous handwritten revisions and strikeouts in the plan, which potentially could impact the readability and comprehension of your HACCP plan's requirements. We suggest that you reassess, update and re-issue this HACCP plan with your signature accepting and implementing the plan.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

When we spoke with you by telephone on June 28, 2004, you promised to make the necessary corrections immediately. Nevertheless, we request that you please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as new or revised HACCP plans or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Shari H. Shambaugh, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Shambaugh at (407) 475-4730.

Sincerely,



Emma R. Singleton
Director, Florida District